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(54) **Gastrostomy tube device for enteral nutrition**

Gastrostomieröhre für enterale Ernährung

Tube de gastrostomie pour nutrition entérale

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(73) Proprietor: **SIS-TER S.p.A.**
26020 Palazzo Pignano (Cremona) (IT)

(72) Inventors:
- **Franchi, Daniele**
  26016 Spino D'adda (Cremona) (IT)
- **Greco, Francesco**
  22060 Cantu' (Como) (IT)
- **Porro, Giampiero**
  22100 Como (IT)

(74) Representative: **Ferroni, Filippo et al**
DRAGOTTI & ASSOCIATI SRL,
Galleria San Babila 4/C
20122 Milano (IT)

(56) References cited:
EP-A- 0 318 918
EP-A- 0 408 198
US-A- 4 225 371
US-A- 4 323 071
US-A- 4 702 252
US-A- 4 863 424
US-A- 5 342 321
US-A- 5 556 385

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Description

[0001] The present invention relates in general to gastrostomic devices for medical use, in particular for the long-term enteric nutrition of patients incapable of the natural ingestion of food and/or medicaments.

[0002] It is known that it is not possible to feed orally and/or to administer drugs orally to patients who are suffering from specific disorders, such as, for example, patients who are comatose or who have lost consciousness.

[0003] In such cases, in addition to the parenteral feeding which is generally adopted for brief periods and normally only for hospitalised patients (a typical example is that of the nutrition and/or pharmacological treatment of patients who are the subject of surgical operations), it is possible to use the so-called enteric route which permits partial use of the digestive system, usually the stomach, excluding the upper portions of the digestive system which cannot be used.

[0004] Within the scope of the enteric route, a solution generally adopted is that of introducing nasally one or more tubes extending as far as the inside of the gastric or intestinal cavity (nasogastric probe or nasojejunal probe).

[0005] This solution has some disadvantages, including principally the discomfort caused to the patient, (as a result of which the so-called compliance is minimal and the periods of use have to be reduced to a minimum), and, secondly, the fact that the substantial length of the above-mentioned tubes and their necessarily small diameter restrict the type of nutrition solely to liquid substances.

[0006] Recent years have seen the proposal and implementation of solutions which may be grouped under the general name of gastrostomic devices which substantially provide for the formation, through the abdominal wall, of a passageway or duct which connects the gastric cavity to the outside, thus permitting the direct introduction of food, also in a form equivalent to the "premasticated" form which normally passes to the stomach during normal nutrition. Of course, although it has considerable limitations, the situation in this case has substantially less serious disadvantages for the patient.

[0007] In practice, a technique known as PEG "Percutaneous Endoscopic Gastrostomy" is initially performed, which consists in introducing a catheter through the oral cavity and the oesophagus until it reaches the stomach; from here the end of the catheter is pulled to the outside through a hole formed in the abdominal wall and the catheter is secured in position by means of a holding tab.

[0008] At this point it is possible to introduce food directly into the gastric cavity for a given time without damaging the upper oesophageal tract and without the problems and disadvantages associated with the use of nasal probes.

[0009] Some time after positioning the catheter, the formation of a type of tissue passageway takes place and at this point it is possible to replace the catheter by a gastrostomic device or tube which is referred to in jargon as a "button" because it is in the form of a button attached to the patient's epidermis.

[0010] The gastrostomic tubes or "buttons" currently in use are principally of two types, namely the "balloon" and "mushroom" types, and they differ from one another principally in the form of the retaining element inside the gastric cavity and in the methods of insertion into the above-mentioned tissue passageway or "stoma" of the patient.

[0011] In the case of the mushroom-type gastrostomic tube, the tube is introduced by means of an obturator inserted into the internal hole of the gastrostomic tube and urged in such a manner as to confer on the mushroom-head retaining element an elongate, substantially conical, profile in order to reduce its diameter and thus to facilitate passage through the stoma, releasing it when it has passed completely into the gastric cavity. However, despite this measure, the operation is not only painful for the patient but also entails the risk of damaging the walls of the stoma especially when removing and/or replacing the device.

[0012] The introduction of the balloon device is easier because it is carried out with the balloon completely deflated and adhering to the tube walls. When the introduction is complete, the balloon is inflated and it thus maintains the end of the gastrostomic tube inside the stomach. The external end of the gastrostomic tube is for its part provided with a plug or a non-return valve which enables the end to be connected periodically to a supply of nutrient material or the like to be introduced into the stomach (in addition to permitting the expulsion of air or gas present in the gastric cavity).

[0013] The length of the gastrostomic tube is of course chosen in accordance with the length of the stoma.

[0014] The balloon-type gastrostomic devices or tubes known and constructed hitherto comprise several components assembled at the manufacturing stage, and therefore require substantial labour, but, in particular, the regions of adhesion of the various components are the critical points of the device, compromising its aesthetic and functional quality.

[0015] Secondly, a periodic check to establish that the internal end of the gastrostomic tube is correctly positioned inside the stomach means that the design of the device must provide for the possibility of radiographic observation.

[0016] Commercially available devices meet this requirement by using for the tubular part a longitudinal strip produced from co-extruded radiopaque material which usually involves the entire thickness of the tube wall.

[0017] This solution involves a weakening of that portion of the device and a reduction in the adhesiveness of the material in the regions where the expanding bal-

loon is to be adhesively bonded.

[0018] Examples of known gastrostomic tube devices reflecting the foregoing state of the art can be found in US Patents No. 5,342,321 and No. 4,863,424.

[0019] The principal aim of the present invention is to provide a gastrostomic tube device which is improved both from the structural point of view and from the functional point of view.

[0020] More specifically, the aim of the present invention is to provide a gastrostomic tube device of which the structure permits practical industrial manufacture and, at the same time, easy location of the position of the device using radiographic techniques.

[0021] This aim is achieved with a device of the type comprising a tubular element which can be inserted through a stoma in the patient's abdominal wall, the tubular element having a first end provided with an inflatable balloon in order to be maintained inside the gastric cavity, and a second end which has a base resting and maintained on the patient's epidermis and which is provided with removable closure means and on-off valve means, characterised in that the tubular element is divided into two ducts, the first duct, having the larger diameter, being used for the passage of the nutritional material and being connected to the removable closure means and to the on-off valve means, and the second duct, having walls produced from radiopaque material, being connected to the inflatable balloon and being provided with a non-return valve arranged at the external end relative to the patient's epidermis, and position-marking means of material opaque to X-rays are provided on the outer surface of the gastrostomic tube.

[0022] In the preferred embodiment of the present invention, the second duct is formed, with a small diameter, in the thickness of the wall of the first duct, the balloon, in the non-inflated state, is constituted by a tubular extension, of variable thickness, of the first end of the tubular element, and the tubular extension is folded back onto the outer surface of the first end of the tubular element and is secured in a sealing manner to the outer surface of the tubular element in such a manner as to envelop the lower outlet mouth of the second duct.

[0023] In addition, the position-marking means are preferably constituted by a thin silver ring which, during the manufacture of the tubular element, is anchored to the outer surface thereof, and is covered by the tubular extension forming the balloon during the adhesive bonding stage.

[0024] The silver ring is used to indicate exactly the position of the proximal point of attachment of the balloon, while a further tube of small thickness produced from radiopaque material is inserted coaxially in the small-diameter duct in order to indicate the position of the tubular portion of the device.

[0025] These and other features and advantages of the present invention will become clear from the following description which is given with reference to the appended drawings, in which:

Figure 1 is a view in longitudinal section of the gastrostomic tube device in the operative state;

Figure 2 is a top view of the gastrostomic tube device;

Figure 3 is a view of the device of Figure 1 in the non-operative state;

Figure 4 is a view similar to that of Figure 3 of a variant and

Figure 5 is a sectional view on the section plane V-V of Figure 3 and Figure 4.

[0026] Referring to the drawings, the gastrostomic tube device according to the invention which, as shown by the Figures, is produced in a single piece from biocompatible plastics material (for example by means of injection or "transfer") comprises a tubular element or body, generally indicated 10, which comprises a first duct or principal duct 12 having a distal end 14 and a proximal end 16. The proximal end 16 starts from a cylindrical or discoidal body 18 and more precisely from a chamber 20 which accommodates a separate and removable non-return valve 22 which can be connected to a bayonet coupling 24 of an elbow connector 26 which can in turn be connected to a supply of nutrient material. The upper end of the chamber 20 is shaped in such a manner as to permit the releasable connection of a plug 28 formed with a strip 30 which is in a single piece with the discoidal body 18 and which is provided with a notch 32 promoting the bending of the strip.

[0027] The discoidal body 18 has a flat base 34, which is to rest on the patient's epidermis in the area of the outer mouth of the stoma or tissue duct of the patient, and, in addition to the chamber 20, comprises a second chamber 36 which accommodates an inflating and non-return valve 38 communicating with the proximal end of a second duct 40 which extends parallel to the duct 12 over a portion of its length and which is formed in the thickness of the wall of the tubular body 10.

[0028] The distal end of the duct 40 has a hole 42 which, as shown in Figure 1, communicates with the inside of the balloon 44, which is shown in that Figure in the inflated position and thus in the position in which it maintains the tubular body 10 inside the gastric cavity.

[0029] It will be readily appreciated from Figures 3 and 4 that the balloon 44 is formed by a tubular extension 50 or 60 of the tubular body 10. In the case of Figure 3, the upstream or proximal end 51 of the tubular extension 50, which is shown in the state before the balloon is inflated, is fixed firmly to the outer surface of the tubular body 10, while the distal end 53 is secured in position when the device is being finished (for example by adhesive bonding or heat-sealing) in the region of the distal end 14 of the tubular body 10.

[0030] As can be seen in Figure 3, the proximal end 51 of the tubular extension 50 envelops the outlet mouth 42 of the second duct 40.

[0031] An alternative embodiment of the device is that represented in Figure 4 which shows how the balloon

44 is in this case formed by a tubular jacket 60 of reduced thickness which is concentric with the tubular body 10. In order to form the balloon 44, the tubular jacket 60 is secured permanently to the outer surface of the tubular body (for example, by heat-sealing or by means of a suitable adhesive) in the area of its distal end 61 once it has been folded back onto the tubular body 10 to the extent that it envelops the mouth 42 of the duct 40. The proximal end 63 of the balloon 60, like the proximal end 51 of the embodiment of Figure 3, is fixed firmly to the outer surface of the tubular body 10.

[0032] In the case of both embodiments, before the heat-sealing or adhesive bonding, a ring of material opaque to X-rays, for example a silver ring 48, is positioned on the outer surface of the tubular body at a predetermined distance from the base 34 of the discoidal body 18, and is simultaneously secured by adhesive bonding to the end 61 of the tubular extension 60 in the case of the embodiment of Figure 4. As shown in Figure 1, the ring is adjacent to the limit of the balloon 44 and therefore, using simple radiography, it is possible to establish from the position of the ring 48 whether the balloon 44 and thus the gastrostomic device is positioned correctly in the gastric cavity.

[0033] It will be readily appreciated from the above description that the device according to the present invention has numerous advantageous aspects.

[0034] Firstly, it can be readily manufactured by unitary moulding from a suitable plastics material and requires only the positioning of the valves 22 and 38, the folding back of the tubular extension 60 onto the body 10 and the adhesive bonding of those two elements only to be ready for use.

[0035] Secondly, it is easy to check that the retaining balloon is positioned correctly inside the gastric cavity.

[0036] Thirdly, it is possible to minimise the extent to which the discoidal body projects from the patient's epidermis. In this connection, it should be pointed out that the drawings are not to scale but are suitably enlarged so that the invention can be better understood.

[0037] The invention has been described in connection with a preferred embodiment but it will be understood that modifications and variants which are equivalent thereto mechanically and in terms of design are possible and can be provided for without departing from the scope of the invention.

Claims

1. Gastrostomic tube device comprising a tubular body (10) which can be inserted through a stoma in the patient's abdominal wall, the tubular body having a first end provided with an inflatable balloon (44) having a proximal end and a distal end in order to be maintained inside the gastric cavity, and a second end having a base resting and maintained on the patient's epidermis, the second end being provided with removable closure means (28) and on-off valve means (22), the tubular body (10) is divided into at least two ducts (12, 40), of which a first duct (12) of larger diameter is suitable for the passage of nutritional material and is connected to the removable closure means (28) and also to the on-off valve means (22), while a second duct (40) is connected to the inflatable balloon (44) and is provided with a non-return valve (38) arranged at the external end relative to the patient's epidermis, **characterised by** the second duct (40) being constituted by a thin-walled tube of material opaque to X-rays, and the device also comprising position-marking means (48) of material opaque to X-rays on the outer surface of the tubular body adjacent to the proximal end of the balloon.

2. Gastrostomic tube device according to Claim 1, **characterised in that** the second duct (40) is formed, with a small diameter, in the thickness of the wall of the first duct (12) using material opaque to X-rays, and **in that** the balloon (44), in the non-inflated state, is constituted by a tubular extension (60) of the first end of the tubular body (10), which extension is folded back onto the outer surface of the first end of the tubular body and is secured in a sealing manner to the outer surface of the tubular body in such a manner as to envelop the lower outlet mouth of the second duct.

3. Gastrostomic tube device according to Claim 1 or Claim 2, **characterised in that** the position-marking means (48) are constituted by a thin silver ring which, during the manufacture of the tubular body (10), is anchored to the outer surface thereof.

4. Gastrostomic tube device according to Claim 3, **characterised in that** the silver ring is anchored to the outer surface of the tubular body (10) in a position adjacent to that of the tubular extension (60) after the latter has been folded back onto the outer surface of the tubular body (10).

5. Gastrostomic tube device according to any one of Claims 2 to 4, **characterised in that** the tubular extension (60) which is to form the balloon (44) and which has a reduced and variable thickness is arranged concentrically on the outside of the tubular body (10), to the outer surface of which it is secured permanently.

6. Gastrostomic tube device according to any one of the preceding Claims, in which the second duct (40) is obtained by overmoulding.

7. Gastrostomic tube device according to any one of Claims 2 to 6, wherein the tubular extension (60) is fixed firmly to the outer surface of the tubular body

(10), to which surface it is secured by the adhesive bonding of one end (61) only.

Patentansprüche

1. Gastrostomische Sondenvorrichtung, bestehend aus einem röhrenförmigen Körper (10), der durch ein Stoma in der Bauchdecke eines Patienten eingeführt werden kann, wobei der röhrenförmige Körper mit einem ersten Ende versehen ist, an dem ein aufweitbarer Ballon (44) mit einem proximalen und einem distalen Ende zur Aufnahme in der Magenhöhle angeordnet ist, und weiterhin ein zweites Ende besitzt, an dem sich ein auf der Epidermis des Patienten ruhendes und gehaltenes Basiselement befindet, wobei besagtes zweite Ende mit einer abnehmbaren Absperreinrichtung (28) ausgestattet ist und ebenfalls eine Auf/Zu-Ventileinheit (22) beinhaltet, und der röhrenförmige Körper (10) in zumindest zwei Kanäle (12, 40) geteilt ist, von denen ein erster Kanal (12) einen größeren Durchmesser aufweist, für die Durchführung von Nährstoffen geeignet und mit der abnehmbaren Absperreinrichtung (28) und auch der Auf/Zu-Ventileinheit (22) verbunden ist, wohingegen ein zweiter Kanal (40) mit dem aufweitbaren Ballon (44) verbunden und mit einem am externen Ende relativ zur Epidermis des Patienten angeordneten Rückschlagventil (38) versehen ist, **dadurch gekennzeichnet, daß** der zweite Kanal (40) aus einem dünnwandigen Rohr besteht, und zwar aus einem für Röntgenstrahlen undurchlässigem Werkstoff, und die Vorrichtung ebenfalls einen auf der Außenfläche des röhrenförmigen Körpers, angrenzend an das proximale Ende des Ballons, angeordneten positionsmarkierenden Gegenstand (48) aus einem für Röntgenstrahlen undurchlässigen Werkstoff beinhaltet.

2. Die gastrostomische Sondenvorrichtung nach Anspruch 1, **dadurch gekennzeichnet, daß** der zweite Kanal (40) mit einem kleinen Durchmesser innerhalb der Wanddicke des ersten Kanals (12) ausgebildet wird und aus einem Werkstoff besteht, der für Röntgenstrahlen undurchlässig ist, und daß der Ballon (44) in nicht-aufgeweitetem Zustand durch eine röhrenförmige Verlängerung (60) des ersten Endes des röhrenförmigen Körpers (10) ausgebildet wird, wobei diese Verlängerung auf der Außenfläche des ersten Endes des röhrenförmigen Körpers zurückgeführt und auf der Außenfläche des röhrenförmigen Körpers abdichtend dergestalt befestigt wird, daß sie die Austrittsöffnung des zweiten Kanals überdeckt.

3. Die gastrostomische Sondenvorrichtung nach Anspruch 1 oder Anspruch 2, **dadurch gekennzeichnet, daß** der positionsmarkierende Gegenstand (48) aus einem dünnen Silberring besteht, welcher bei der Herstellung des röhrenförmigen Körpers (10) auf der Außenfläche desselben befestigt wird.

4. Die gastrostomische Sondenvorrichtung nach Anspruch 3, **dadurch gekennzeichnet, daß** der Silberring auf der Außenfläche des röhrenförmigen Körpers (10) an einer Stelle angeordnet ist, die an die röhrenförmige Verlängerung (60) angrenzt, nachdem letztere auf der Außenfläche des röhrenförmigen Körpers (10) zurückgeführt worden ist.

5. Die gastrostamische Sondenvorrichtung nach zumindest einem der Ansprüche 2 bis 4, **dadurch gekennzeichnet, daß** die den Ballon (60) bildende und eine reduzierte und variable Dicke aufweisende röhrenförmige Verlängerung konzentrisch auf der Außenseite des röhrenförmigen Körpers (10) angeordnet ist, auf dessen Außenfläche sie dauerhaft befestigt wird.

6. Die gastrostomische Sondenvorrichtung nach zumindest einem der vorgenannten Ansprüche, bei der der zweite Kanal (40) durch Überformen ausgebildet wird.

7. Die gastrostomische Sondenvorrichtung nach zumindest einem der Ansprüche 2 bis 6, **dadurch gekennzeichnet, daß** die röhrenförmige Verlängerung (60) fest mit der Außenfläche des röhrenförmigen Körpers (10) verbunden ist, an dessen Oberfläche sie lediglich durch den adhäsiven Verbund eines Endes (61) befestigt wird.

Revendications

1. Dispositif à tube de gastrostomie comprenant un corps tubulaire (10) qui peut être inséré à travers une stomie dans la paroi abdominale du patient, le corps tubulaire ayant une première extrémité proposée avec un ballon gonflable (44) ayant une extrémité proximale et une extrémité distale afin d'être maintenu à l'intérieur de la cavité gastrique, et une seconde extrémité ayant une base qui reste et qui est maintenu sur l'épiderme du patient, la seconde extrémité étant pourvue d'un moyen de fermeture amovible (28) et d'un moyen de soupape marche-arrêt (22), le corps tubulaire (10) est divisé en au moins deux conduits (12,40), dont un premier conduit (12) de plus grand diamètre est approprié au passage d'élément nutritionnel et est relié au moyen de fermeture amovible (28) et aussi au moyen de soupape marche-arrêt (22), alors qu'un second conduit (40) est relié au ballon gonflable (44) et il est pourvu d'un clapet de non-retour (38) disposé à l'extrémité externe par rapport à l'épiderme du patient, **caractérisé en ce que** le second

conduit (40) est constitué par un tube à paroi mince en matière opaque aux rayons X, et que le dispositif comprend aussi un moyen de marquage de position (48) en matière opaque aux rayons X sur la surface extérieure du corps tubulaire adjacent à l'extrémité proximale du ballon.

2. Dispositif à tube de gastrostomie selon la revendication 1, **caractérisé en ce que** le second conduit (40) est formé, avec un petit diamètre, dans l'épaisseur de la paroi du premier conduit (12) en utilisant une matière opaque aux rayons X, et **en ce que** le ballon (44), à l'état de non-gonflement, est constitué par une extension tubulaire (60) de la première extrémité du corps tubulaire (10), cette extension étant repliée sur la surface externe de la première extrémité du corps tubulaire et étant fixée hermétiquement à la surface externe du corps tubulaire de telle façon qu'elle enveloppe la bouche de sortie inférieure du second conduit.

3. Dispositif de tube de gastrostomie selon la revendication 1 ou la revendication 2, **caractérisé en ce que** les moyens de marquage de position (48) sont constitués d'un mince anneau d'argent qui, pendant la fabrication du corps tubulaire (10), est ancré à la surface externe de celui-ci.

4. Dispositif de tube de gastrostomie selon la revendication 3, **caractérisé en ce que** l'anneau d'argent est ancré à la surface externe du corps tubulaire (10) dans une position adjacente à celle de l'extension tubulaire (60), une fois que cette dernière a été rabattue sur la surface extérieure du corps tubulaire (10).

5. Dispositif de tube de gastrostomie selon l'une quelconque des revendications 2 à 4, **caractérisé en ce que** l'extension tubulaire (60) qui forme le ballon (44) et qui a une épaisseur réduite et variable est disposée sur l'extérieur du corps tubulaire (10), concentriquement à la surface externe à laquelle elle est fixée de façon permanente.

6. Dispositif de tube de gastrostomie selon l'une quelconque des revendications précédentes, dans lequel le second conduit (40) est obtenu par surmoulage.

7. Dispositif de tube de gastrostomie selon l'une quelconque des revendications 2 à 6, dans lequel l'extension tubulaire (60) est fixée fermement à la surface externe du corps tubulaire (10), surface à laquelle elle est fixée par un collage adhésif à une extrémité (61) uniquement.

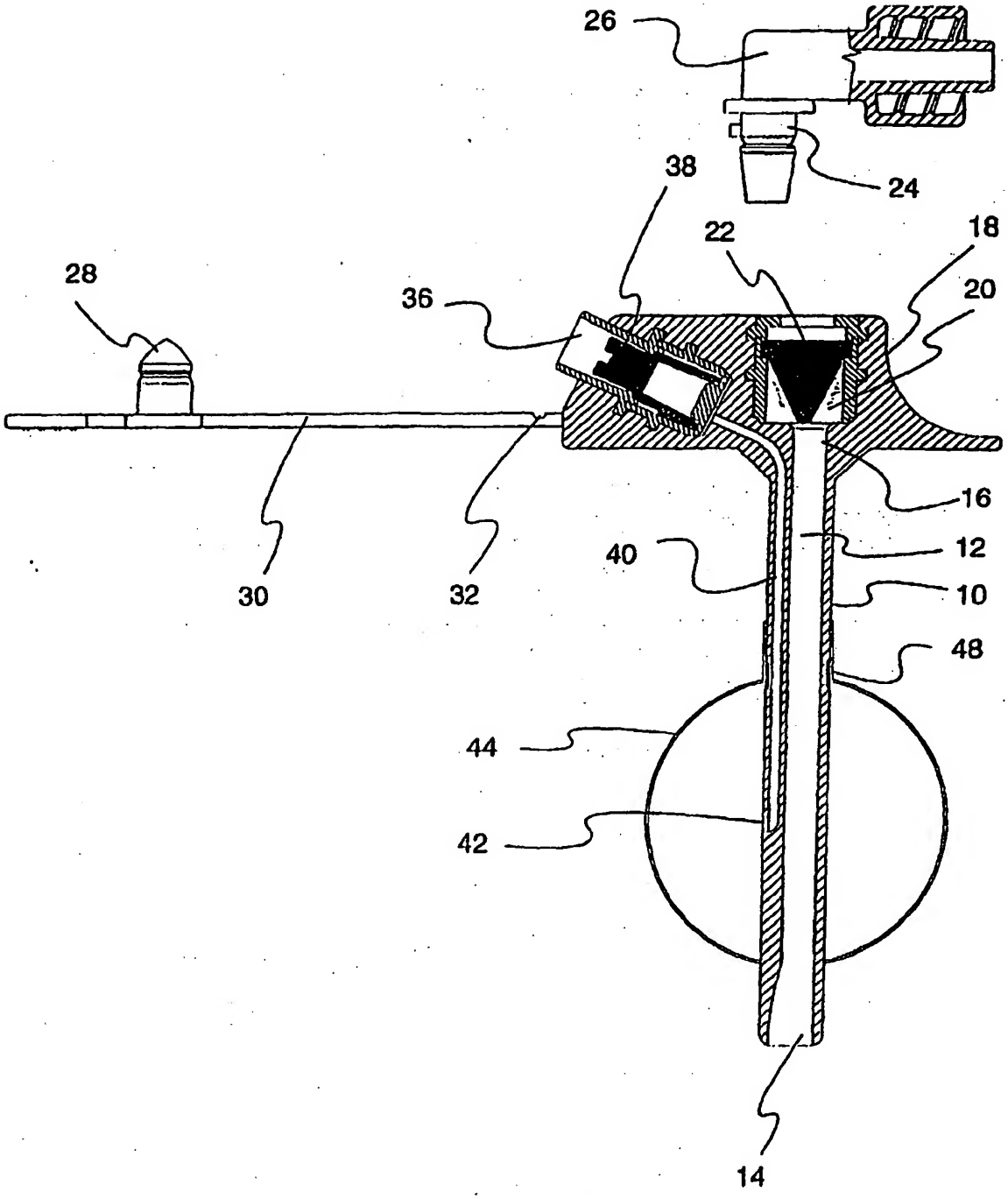

Fig. 1

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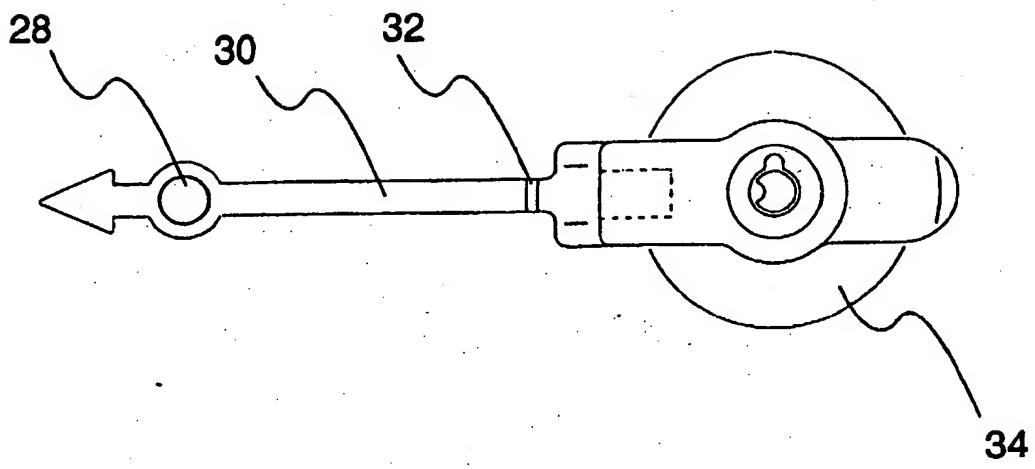

Fig. 2

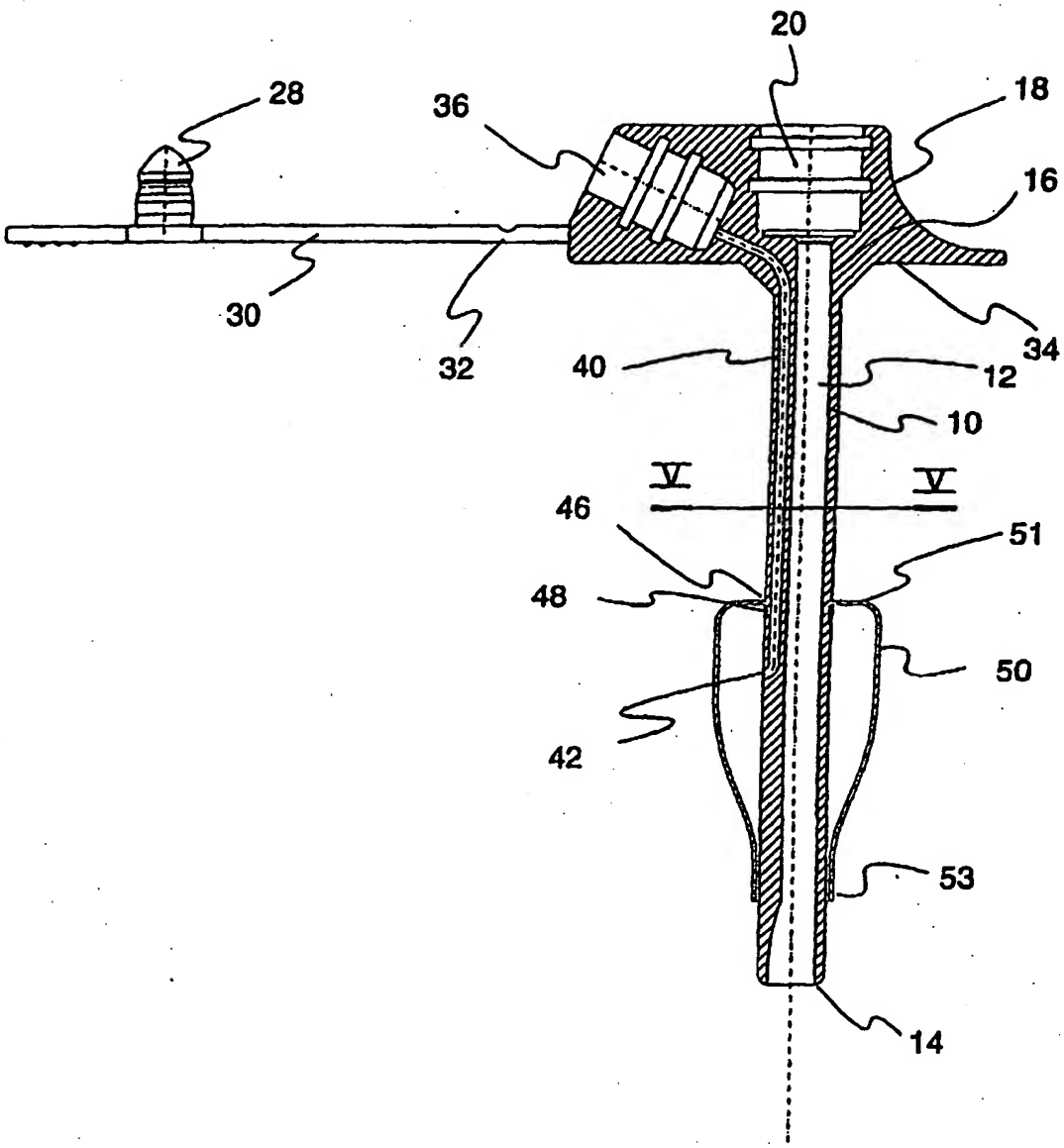

Fig. 3

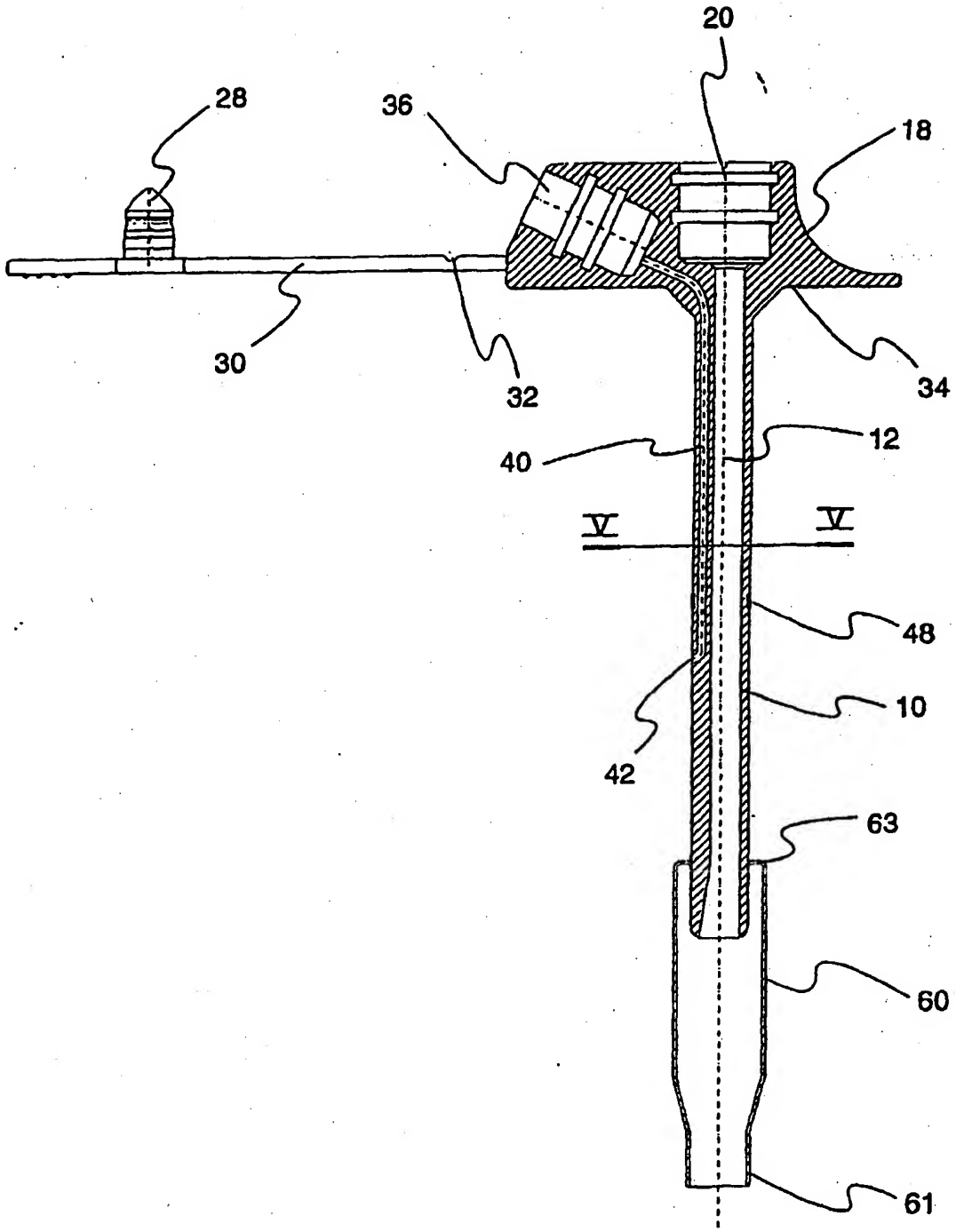

Fig. 4

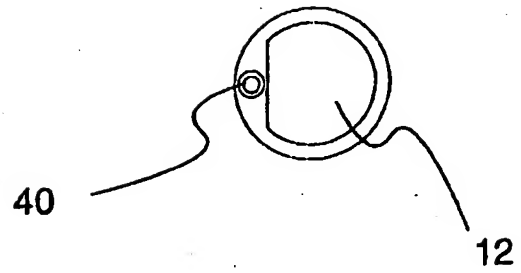

Fig. 5